Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1054282	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier M D Express Urgent Care - Yorktown	**Street Address, City, State** 4740 George Washington Memorial Highway, Yorktown, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced on-site CLIA recertification survey was conducted at MD Express-Yorktown on November 18, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 11/2/2020 and virtual record review conducted on 11/5/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's package insert instructions, and interviews, the laboratory failed to follow cardiac and lipid chemistry quality control (QC) storage requirements for eight (8) of 8 reagent kits on the date of the inspection on November 18, 2020. Findings include: 1. During a tour of the laboratory on 11/18/20 at approximately 1:30 PM, the inspector noted a bench top freezer with a Fisher Scientific Traceable digital temperature whose reading was -11 C. The freezer was labeled with printed directions: "Temp for this freezer must be -18 Degrees or below". The inspector inquired of the staff regarding the temperature monitoring of the freezer. The testing personnel stated: "We store Quidel Triage and Piccolo chemistry quality control vials in there. We are now putting our send out COVID-19 test samples in there for courier pick up. We do open it many times a day to put the COVID samples in and that makes the temperature vary." The inspector noted approximately twelve (12) send out samples bagged for LabCorp reference laboratory and the following eight (8) boxed chemistry reagents stored in the freezer: Two (2)

	boxes of NOD Liquid Assayed Chemistry Lipid Controls (Lot Numbers 465020002 and 465020003); Three (3) boxes of Quidel Triage Total 5 Controls Level 1 (Lot Number C3553AN); Three (3) boxes of Quidel Triage Total 5 Controls Level 2 (Lot Number C3577AN). 2. Review of the NOD Lipid Control package revealed storage temperature instructions "store at -15 C to -25 C". Review of the Quidel outer package revealed storage temperature instructions as - 20 C. The package insert stated: "The Quidel Triage Total 5 Controls are assayed materials to be used with Quidel Triage Cardiac Panel for Triage Meters to assist the laboratory in monitoring patient test performance. Store frozen at -20 C or colder in non-defrosting freezer. Do not store near the freezer door. Controls should not be used if thawed upon receipt. Controls should not be refrozen." 3. The inspector inquired of the office manager and coordinator to describe the temperature monitoring protocols for the bench top freezer. The office manager stated, at approximately 2:00 PM: "The staff normally record the temperatures in the morning before the freezer is opened and it is in range. We had not thought about the temperature fluctuations due to opening it so many times during the day for adding the COVID-19 send outs". The laboratory coordinator stated "As far as I know by looking back at the temp logs, the freezer has been in range every day when checking it. My guess is that with constant opening and shutting to put specimens in its been going up and down. This is the first time I've heard about this so I'll be checking on it for a solution." 4. In an exit interview with the office manager and coordinator at approximately 2:30 PM, the above findings were confirmed.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of procedures, quality assurance (QA) records, lack of documentation, and an interview, the laboratory failed to document a validation or check of their hematology and chemistry analyzer's automated interfaces in order to verify transmission of Complete Blood Count (CBC), Creatine Kinase Myocardial Band (CK-MB), Myoglobin, and Troponin (cTn1) results from May 2020 to the date of the laboratory tour on November 18, 2020. Findings include: 1. During an entrance interview with the laboratory's coordinator on 11/5/20 at approximately 1:00 PM, the inspector was informed that the laboratory no longer manually entered CBC, CK-MB, Myoglobin, or cTn1 results into the patient electronic medical record (EMR). The facility had purchased an information system (LabDaq) in May 2020 that interfaced the Medonic hematology and Triage chemistry analyzers to the EMR. 2. Review of the laboratory's QA procedures revealed no record of a validation of the LabDaq electronic interface for the transmission of the Medonic CBC or Triage Cardiac Panel results from the date of the interface installation in May 2020 to the date of the virtual record review on 11/5/20. The inspector requested to review validation documentation of the LabDaq transmission of patient results. The coordinator stated on 11/5/20 at

	approximately 2:30 PM: "I will check with LabDaq and ask for the validation data". 3. During the onsite tour on 11/18/20, the inspector requested to review validation documentation of the LabDaq transmission of patient results. No records were available for review. 4. In an exit interview with the office manager and coordinator at approximately 2:30 PM, the above findings were confirmed.